

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,413	04/24/2001	Francis P. Barry	640100-424	5476
7590 04/19/2007 Raymond J. Lillie, Esq. c/o Carella, Byrne, Bain, Gilfillan Cecchi, Stewart & Olstein 6 Becker Farm Road Roseland, NJ 07068			EXAMINER	
			MATTHEWS, WILLIAM H	
			ART UNIT	PAPER NUMBER
			3738	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
2 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.





Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/841,413

Filing Date: April 24, 2001 Appellant(s): BARRY ET AL. MAILED

APR 1 9 2007

GROUP 3700

Raymond J. Lillie For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11-13-06 appealing from the Office action mailed 1-12-06.

Art Unit: 3738

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,482,231 B1 Abatangelo et al. 11-2002

WO 98/51317 A1 Goldberg et al. 11-1998

Art Unit: 3738

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28, 31-33, 35, 38-40, 42, 45-47, 49, 52-54, 56, and 59-61 stand rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al. WO 98/51317 A1.

Goldberg et al. disclose regenerating meniscal tissue (p4, line 33 – p5, line 9) by injecting a suspension including an effective amount of mesenchymal stem cells (p4, lines 7-16 and p17, lines 11-21) into the knee joint space (p6, lines 1-9). Although Goldberg et al. lack the express statement of regenerating "meniscal" tissue, Goldberg et al. discloses all steps of the claimed method and discloses regeneration of a plethora of tissues (p4-5). Therefore the method of Goldberg et al. would inherently regenerate meniscal tissue.

Claims 28-30,34-37,41-44, 48-51, 55-58, 62, and 63-77 stand rejected under 35 U.S.C. 102(e) as being anticipated by Abantangelo et al. US PN 6,482,231.

Art Unit: 3738

Abatangelo et al. disclose injection of a mesenchymal cell suspension with a concentration of about $1 \times 10^4 - 1.5 \times 10^8$ cells per ml (col. 8 lines 13-37). The suspension may include sodium hyaluronate (see column 7, lines 20-43 of USPN 5,676,964 or column 18, lines 48-53 of USPN 4,851,521, both incorporated by reference at column 6, lines 52-59). The suspension may be used for meniscal tissue repair (column 14, lines 38-54).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

(10) Response to Argument

Abatangelo et al.

Applicant contends Abatangelo et al. only provide a generic disclosure encompassing the claimed subject matter and therefore lack the specificity necessary to anticipate. For example, Applicant acknowledges Abatangelo et al. contemplates solid or fluid matrices including mesenchymal stem cells, but the preferred Examples only describe solid implants for repair of meniscal tissue (Arguments page 6, first paragraph). Examiner disagrees with Applicant's analysis because the disclosure of Abatangelo et al. is not limited to embodiments recited in Examples 1-11 because the

Art Unit: 3738

disclosure of Abantangelo et al. must be interpreted in its entirety. Applicant provides Walsh <u>Tissue Engineering</u> (Arguments pages 9-11) to suggest it would not have been obvious to utilize the liquid suspension (disclosed by Abatangelo et al.) as an alternative to the solid implants described in the Examples. However, the rejection is one based on anticipation and not obviousness, and therefore, the teachings of Walsh are not relevant.

Goldberg et al.

Applicant contends Goldberg et al. lack guidance as to providing an effective amount of mesenchymal stem cells to regenerate meniscal tissue (Arguments page 11, final paragraph). Applicant cites specific examples of Goldberg et al. directed to repair of articular cartilage (Arguments page 17, final paragraph) and cartilaginous tissue (Arguments page 18), and further describes the differences between meniscal tissue and articular cartilage. Due to the explicit teaching of repairing articular cartilage, Applicant states the method of Goldberg et al. would not regenerate meniscal tissue. Examiner disagrees because Goldberg et al. disclose the "effective amount" of cells (see Goldberg et al., pages 10 and 17 citing 10-50 million mesenchymal stem cells), which are injected into the synovial space of the knee joint, and would inherently produce meniscal tissue. Applicant's specification at page 5, second paragraph provides support of the Examiner's conclusion:

Art Unit: 3738

Thus, the mesenchymal stem cells, when administered to a joint, are capable of replacing missing and/or damaged tissue in the joint, including meniscal tissue. Thus, the administration of mesenchymal stem cells to a joint provides for regeneration of cartilaginous tissue, including meniscal tissue, in the joint, thereby providing for repair and stabilization of the joint, as well as reducing pain in the joint and reducing subchondral bone sclerosis.

Applicant's specification acknowledges the administration of mesenchymal stem cells to the knee joint provides regeneration of cartilaginous tissue, including meniscal tissue rather than solely meniscal tissue. Therefore, although Goldberg et al. fails to expressly list meniscal tissue as one of the many cartilaginous tissues regenerated in the method, it is clear that meniscal tissue would have been inherently regenerated.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

William H Matthews

Conferees:

Tom Barrett

Corrine McDermott

CORRINE McDERMOTT SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700